



ANSI-ASQ National Accreditation Board / ACCLASS

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- Laboratories – ISO/IEC 17025
- Inspection Bodies – ISO/IEC 17020
- RMPs – ISO Guide 34 (Reference Materials)
- PT Providers – ISO 17043
- Product Certifiers – ISO Guide 65
- Government Programs: DoD ELAP, EPA Energy Star, CPSC Toy Safety, NRC, NIST IPV6, NLLAP, NEFAP
- TRAINING Programs

- Certification Bodies – *ISO/IEC 17021*
- *Accreditation for Management System Certification Bodies that certify to:*
 - *ISO 9001 (QMS),*
 - *ISO 14001 (EMS),*
 - *TS 16949 (US Automotive) etc.*



Examples of U.S. Regulators Embracing Accredited 3rd Party

- ★ Department of Defense
- ★ Consumer Product Safety Commission
- ★ Department of Energy
- ★ Nuclear Regulatory Commission
- ★ Environmental Protection Agency
- ★ National Institute of Standards and Technology
- ★ Department of Justice
- ★ Federal Communications Commission
- ★ Food and Drug Administration
- ★ Department of Homeland Security
- ★ Federal Aviation Administration



Location of ACLASS and ANAB Offices

- ACLASS → 500 Montgomery St.
Suite 625
Alexandria, VA 22314
- ANAB → 600 N. Plankinton Ave.
Suite 300
Milwaukee, WI 53203



ACCLASS Parents / Owners

- **ANSI** – American National Standards Institute
(offices in “L” St. in Washington, D.C.
and W. 43rd St. in New York City)
- **ASQ** – American Society for Quality
(same address as ANAB) – ASQ bldg.



ACCLASS Contact Persons

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 - Roger Muse, Sales
- Technical – Geneva Bowman
 - Larry Jackson
 - Bill Hirt, PhD
- Admin / Scheduling – Erica Collins



ACCLASS DoD ELAP Accreditations

- Working closely with 25+ laboratories
- 19 DoD ELAP accreditations completed / 9 posted since last year's EMDQ
- Average findings per report ~ 40



Common Deficiencies

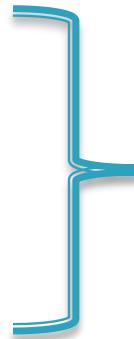
- Break into 3 sections, based on the structure of the QSM 4.2 standard:
 - Management requirements (clause 4)
 - Technical requirements (clause 5)
 - Appendix sections



Management Requirements

– deficiency summary

- Most frequent elements:
 - 4.2 (quality system)
 - 4.3 (document control)
 - 4.12 (records)
- Improvement in 4.1 (organization)
- All remaining elements < 5%

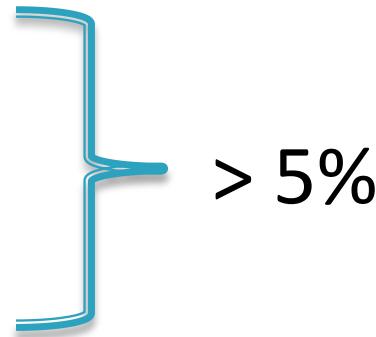


> 5%

Technical Requirements

– deficiency summary

- Most frequent elements:
 - 5.4 (test methods)
 - 5.5 (equipment)
 - 5.9 (assuring results)
- Improvement in 5.8 (handling of samples)
- All remaining elements < 5%



Appendix Section of QSM 4.1/4.2

– deficiency summary

- Most frequent elements:
 - Appendix D (essential QC requirements)
 - Appendix E (SW-846 reporting requirements)
 - Appendix F (SW-846 QC requirements)

- Least frequent elements:
 - Appendix C and G < 1.5%



Common Opportunities (OFI)

- Management Requirements
 - Section 4.2
 - Section 4.10 (Corrective Action)
- Technical Requirements
 - Section 5.4
 - Section 5.5
 - Section 5.9

Complaints

- Confusion of available methods for DoD scope
- Confusion of DENIX upload timeframe
- Tracking and Maintenance of PT results



Current Assessment Issues – 1

- PT Diligence by Accredited Labs
- Tracking PT – Excel
- Mobile Labs
 - Alaska Example
 - Mobile Trailers



Current Assessment Issues – 2

- Labs misunderstanding of advance requirements & assessment requirements
 - Significant delays in document submissions
 - Lack of readiness with LOD/LOQ
- Inclusion of ISO 17025

Proposed Changes to QSM 5.0

- Reduce Frequency of LOD/LOQ
- Reduce Duplication of Requirements
- Simplify Requirements wherever possible

Common Trends

- Frequent Requests for Scope Expansions
- Laboratory Customers/Contractors Request for additional scope coverage



Questions